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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,665	06/28/2004	Arturo Leone	206,588	3094

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EXAMINER	
STOICA, ELLY GERALD	
ART UNIT	**PAPER NUMBER**
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,665	LEONE ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-32,34-47 and 50-72* is/are pending in the application.

4a) Of the above claim(s) *34,39-45 and 54-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-32,35-38,46,47,50-53 and 62-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. In the response to the non-final rejection filed on 12/06/2007, Applicant cancelled claims 33, 48 and 49, amended claims 30-32, 35-38, 46-47, 50-53 and 32 and added new claims 63-72. Claims 30-32, 34-47, 50-72 are pending. Claims 34, 39-45 and 54-61 are withdrawn. Claims 30-32, 35-38, 46-47, 50-53, 62-72 are currently examined.

Specification

2. The disclosure is objected to because of the following informalities: on page 16, lines 8-9 contain text in the Italian language.

Appropriate correction is required.

Claim Objections

3. Claims 1, 37, 38, 46, 53, and 62, are objected to because of the following informalities: the claims should contain the appropriate article, either definite or indefinite ("a" or "the"). Appropriate correction is required.

4. Claim 31 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. As presented, the claim is expanding the scope of the independent claim 30, by claiming a lower sequence homology then 100%.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 30, 32, 38, 50-53 and 63-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, it is not clear for the claims 30, 32, 50-53 and 63-72 how the intended use would further limit the antibody. Thus, the metes and bounds of the claim cannot be determined.

For claim 38, it is unclear what the relation with claim 35 is. It is unclear if the MAP constructs claimed are made in the hybridomas of claim 35 or not.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 35-38, 47, 53, 69-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that the monoclonal antibodies secreted by the hybridomas AC-1, AC-2, AC-3, AC-4, AC-5, AC-6, AC-7, AC-8 and AC-9 are required to practice

the claimed invention. As such the biological material should be readily available or obtainable by a repeatable method set for the in the specification, or otherwise readily available to the public, If it is not so obtainable or available, the requirement of USC 112 first paragraph, may be satisfied by a deposit of the biological material needed to obtain the said antibodies. If a deposit is made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by the applicants, or a statement by an attorney of record over her or his signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon issuance of a patent, would satisfy the deposit requirement made herein, If a deposit has not been made under the terms of the Budapest Treaty, than in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, the Applicant may provide assurance that compliance by statement , affidavit , declaration or a statement by an attorney of record over her or his signature and registration number , or someone empowered to make such a statement, showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or five years after the last request or for enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of the deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

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5. Claim 31 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

As iterated in the previous Office action, the claim is drawn to a genus of peptides that is defined only by sequence identity. the description of polypeptide species (Seq. Id. Nos.: 15, 16, 17, 18) is not adequate written description of an entire genus of functionally equivalent polypeptides which incorporate all variants and fragments and with at least 75%, 80%, 90%, 95%, and 98% sequence homology to a peptide selected from the group of sequences identified as Seq. Id. Nos.: 15, 16, 17, 18. The remaining 2-25% of the protein or peptide is not described until its reduction to practice. Therefore, only the Seq. Id. Nos.: 15, 16, 17, 18, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

On page 9 of their Remarks Applicants argue that, as amended, claim 31 is a dependent claim and the written description rejection should be withdrawn. The arguments were carefully considered but not found persuasive because as presented in

the objection to claim 31, does not further limit claim 30, and therefore is being considered on its own merits in the interest of compact prosecution.

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6. Claims 30-32, 35-38, 46-47, 50-53 and 62-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for research purposes, specifically detection of BAG 3 protein, does not reasonably provide enablement for diagnostic and therapy or inhibition of BAG3 protein activity or increasing apoptosis in primary cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

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7. The claims are drawn to antibodies that recognize or inhibit BAG3 protein activity and fragments thereof characterized in that they are used in research, diagnostics and therapy for cell death-involving diseases, and for the modulation of cell survival and/or death, said protein and fragments being selected from the group of peptide sequences identified as SEQ ID NO: 15, 16, 17, 18. The antibodies are intended for use in the

treatment of neoplastic disease. The antibodies would recognize the Seq. Id. Nos. 15-18 of the BAG3 protein and clearly can be used for detection. For the antibodies to be used in diagnosis, a clear relationship between any disease and the expression levels of the protein BAG 3 should have been established first. The state of the art is not aware of a clear connection between the level of expression of BAG 3 protein and a disease. The specification presents data regarding the expression of BAG 3 in leukemic cells from B-CLL or ALL patients or in the human cell line U397. However the data presented does not establish the BAG3 expression as a diagnostic marker since there are a great number of controls missing as is a comprehensive biostatistical analysis. The detection of BAG 3 by the antibodies of the instant Application accomplishes just that: detection, without any correlation with a recognized diagnostic marker. Moreover, the specification does not present and the art is not aware of, evidence of diseases characterized by an excess or diminished level of BAG3. The fact that in some human primary leukemic cells or SAOS cell line or U937 cell line apoptosis is enhanced when using antisense oligonucleotides does not constitute in any way proof that the levels of BAG protein are involved in the etiology of the disease or to have diagnosing potential. Currently, there is no clinical association of any disease with BAG 3 levels.

It is noted that, as known in the art and disclosed in the Specification, the BAG 3 protein is an intracellular protein without access to the cellular membrane. In order to have any effect (i.e. inhibition) on the protein activity, the monoclonal antibodies claimed would have first to interact with the said protein. Such an access is not possible from the outside of the cells, as exemplified by the works of Schietinger et al. (Science, 314, 304-

308, 2006, abstract). In order for the antibody to be effective against an intracellular protein it has to be expressed, as a fragment antibody, within the cell (as intrabodies) so as to affect the activity of an intracellular protein (Lobato et al., Curr. Mol. Med., 4, 519-528, 2004, abstract, figs. 1-3 and table 1). This is clearly not the case for the monoclonal antibodies claimed as claimed in the Application. In the best case scenario, the antibodies could affect the BAG-3 in vitro by microinjecting the antibodies in the cell in culture, but this aspect is not addressed in the specification.

Regarding the therapeutical use of the antibodies, as iterated supra, in order for an antibody to affect the activity of the protein, the antibody has to have access, in vivo, to the protein, which is not possible while a cell is still living, as required for therapy. The state of the art, at the time that the invention was made, recognizes the use of specific antibodies for specific diseases, as evidenced by the prior art cited by Applicant. However, for the antibody-based therapy, the use of each antibody in the method of treatment would be a lengthy, unpredictable and extremely experimentation intensive process since the art teaches against the use of monoclonal antibodies for intracellular proteins. Consequently, there is no **therapeutic** benefit associated with the use of the claimed antibodies for any disease. The specification does not offer any guidance as to the specific conditions actually treated or diagnosed. The amount of experimentation needed to **use** the antibodies as claimed is considered undue and therefore the specification is not enabling for the invention as claimed.

Therefore, given the state of the art which is not aware of the possibility of affecting the activity of an intracellular protein by a monoclonal antibody, the lack of

guidance and working examples regarding the use of these antibodies for inhibiting the activity of BAG 3 protein or to diagnose a disease based on the BAG3 detection as well as the use of the antibodies in therapy, the amount of experimentation needed to use the antibodies in a manner commensurate with the scope of the claims is considered undue.

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8. On page 11 of the Remarks Applicants argue that no undue experimentation should be required to obtain the antibody. Also Applicant argues on page 14 that the antibodies where obtained in a process of **purposive selection**. The arguments were carefully considered but not found persuasive because as presented supra, it is not the process of obtaining the antibodies that is not enabled but the use of the obtained antibodies for the purposes claimed. While the antibodies may be used for recognition of BAG3 for instance for research purposes, there is no indication that they would be able to be used for diagnostic or therapeutic purposes. In the specification, as iterated supra, there is no indication that the antibodies where designed with a specific purpose in mind, since there is no example that they can be used for anything else that recognizing the BAG 3 protein, which actually can be achieved with any antibody against the protein. Moreover, the Lopez-Guillermo et al. article provided by the Applicant in support for the enablement argument clearly deals with clinical use of antibodies which recognize **cell surface receptors**. As Applicant is well aware, the BAG3 protein is not expressed at the cell surface, hence it cannot be targeted *in vivo* with “therapeutic” antibodies. Therefore, the claims 30-32, 35-38, 46-47, 50-53 and 62 remain and the claims 63-72 are rejected under 35 U.S.C. 112, first paragraph, as

failing to comply with the enablement requirement. While intended use is not given weight in applying the prior art, any intended use recited in the claim must be examined for enablement under 35 U.S.C. §112, first paragraph. For reasons cited in the previous Office Action and above, the intended uses for diagnostics, therapy, inhibiting BAG3 activity in vivo and increasing cell death are not enabled.

Claim Rejections - 35 USC § 103

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. Claims 30-32, 46, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Pat. 6,696,558).

The claims are drawn to antibodies that recognize or inhibit BAG3 protein activity and fragments thereof characterized in that they are used in research, diagnostics and therapy for cell death-involving diseases, and for the modulation of cell survival and/or

death, said protein and fragments being selected from the group of peptide sequences identified as SEQ ID NO: 15, 16, 17, 18. The antibodies are part of a composition or a kit.

Reed et al discloses antibodies specific for the human BAG family protein including monoclonal antibodies that retain binding activity, or chimeric antibodies or humanized antibodies. The polypeptide of Seq. Id. No: 20 used by Reed et al. to obtain the antibodies is the mature BAG3 polypeptide and the fragments of Seq. Id. Nos.: 15, 16, 17, 18 of the instant application are comprised in the sequence presented by Reed et al. Such peptide antibodies may be raised against **any BAG domain of any of the human BAG proteins** (col. 11, lines 32-62). The antibodies would necessarily have all the binding and functional properties conferred by the epitope that they are raised against.

Seq. Id. No: 15 of the current application is identical with the amino acids 18-33 of the Seq. Id. No.: 20 in the Reed et al patent (which is the human BAG-3 amino acid sequence).

Seq. Id. No: 16 of the current application is identical with the amino acids 389-399 of the Seq. Id. No.: 20 in the Reed et al. patent (which is the human BAG-3 amino acid sequence).

Seq. Id. No: 17 of the current application is identical with the amino acids 533-547 of the Seq. Id. No.: 20 in the Reed et al. patent (which is the human BAG-3 amino acid sequence).

Seq. Id. No: 18 of the current application is identical with the amino acids 561-575 of the Seq. Id. No.: 20 in the Reed et al. patent (which is the human BAG-3 amino acid sequence).

Reed et al. does not specifically teach the specific monoclonal antibodies of the instant Application.

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have used fragments of the BAG 3 to raise antibodies against the protein with a good expectation of success because Reed et al. teaches that monoclonal antibodies can be obtained against any fragment of BAG 3. The number of antigenic peptide stretches is limited and the art was well aware of choosing antigenic peptides for raising antibodies. The motivation to do so is that a person of ordinary skill in the art is always motivated to pursue the known options within her or his technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

On pages 14-17 Applicants argue that: the disclosure of the Reed et al. patent is hypothetical and that the antibodies of the instant Application were obtained by a purposive selection and therefore they have properties that distinguish them from the antibodies of Reed et al.

The arguments were carefully considered but not found persuasive because the sequences envisioned by the Applicant are an integral part of the sequence used by Reed et al. and any antigenic peptide of the sequence can be used for raising the antibodies, as taught by Reed et al. While not contending that the antibodies of Reed et

al. are identical to the antibodies of the instant Application, it also noted that the claimed antibodies have no particular properties that would have made them unobvious over the prior art. Claiming purposive selection is just an argument that is not backed by any fact disclosed in the specification. There is nothing special regarding the recognition of the BAG 3 protein that antibodies raised , as taught by Reed et al., for example against amino acid 18-33, 389-399, 533-547 or 561-575 of the BAG 3 amino acid sequence, that the antibodies of the instant Application would perform and the antibodies of Reed et al. would not be able to perform. Therefore, the claims 30-32, 46, and 62 are considered obvious over Reed et al.

11. Claims 30-32, 46 and 62 rejected under 35 U.S.C. 103(a) as being unpatentable over Kohn et al. (U.S. Pat. 5, 652,223). Formatted: Bullets and Numbering

Kohn et al teach antibodies against the Carboxyamido triazole (CAI) resistance protein (CAIR-1) (Seq. Id. No: 2). The fragments of Seq. Id. Nos.: 16, 17, 18 of the instant application are comprised in the sequence presented by Kohn et al The antibody may be raised against synthetic peptides made using CAIR-1 sequences. Either monoclonal or polyclonal antibodies were generated, for subsequent use in immunoassays to measure the protein (col. 18, line 22 to col. 19 line 9). Kohn et al. also teach kits for detecting the presence of CAIR proteins in tissue or blood samples which comprise a container containing antibodies selectively immunoreactive to the protein and instructional material for performing the test. The kit may also contain other components such as CAIR proteins, controls, buffer solutions, and secondary antibodies (col. 21, lies 1-6).

Seq. Id. No: 16 of the current application is identical with the amino acids 51-65 of the Seq. Id. No.: 2 in the Kohn et al. patent.

Seq. Id. No: 17 of the current application is identical with the amino acids 199-213 of the Seq. Id. No.: 2 in the Kohn et al. patent.

Seq. Id. No: 18 of the current application is identical with the amino acids 227-241 of the Seq. Id. No.: 2 in the Kohn et al. patent.

The antibodies would necessarily have all the binding and functional properties conferred by the epitope that they raised against.

Kohn et al. does not specifically teach the specific monoclonal antibodies of the instant Application.

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have used fragments of the BAG 3 to raise antibodies against the protein with a good expectation of success because Kohn et al. teaches that monoclonal antibodies can be obtained against synthetic peptides made using CAIR-1 sequences. The number of antigenic peptide stretches is limited and the art was well aware of choosing antigenic peptides for raising antibodies. The motivation to do so is that a person of ordinary skill in the art is always motivated to pursue the known options within her or his technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

On pages 14-17 Applicants argue that antibodies of the Kohn et al. patent are hypothetical and that the antibodies of the instant Application were obtained by a purposive selection and therefore they have properties that distinguish them from the

antibodies of Kohn et al. Also argued is the allegedly teaching away of Kohn et al. on the basis that BAG3 protein inhibits the assistance provided by hsp70 chaperone activity for the refolding of test protein.

The arguments were carefully considered but not found persuasive because the sequences claimed are comprised in the sequence of Kohn et al and any antibody raised against an antigenic peptide as present in Kohn et al. sequence would necessarily bind BAG-3 and have the inherent property conferred by its antigenic determinant. Regarding the “teaching away” argument, Examiner could not find the alleged teaching mentioned by Applicant which mistakenly cited columns in the Kohn et al. patents that do not contained the alleged teaching, as they are not present in any portion of the disclosure of the patent. Even if such a teaching had existed, it would have been irrelevant to the prosecution of the Application, since it is the actual properties of the antibody and not the intended use that are offered patentability weight. While not contending that the antibodies of Kohn et al. are identical to the antibodies of the instant Application, it also noted that the claimed antibodies have no particular properties that would have made them unobvious over the prior art. Claiming purposive selection is just an argument that is not backed by any fact disclosed in the specification. There is nothing special regarding the recognition of the BAG 3 protein that antibodies raised , as taught by Kohn et al., for example against amino acid 51-65, 199-213, 227-241 of the CAIR-1 amino acid sequence, that the antibodies of the instant Application would perform and the antibodies of Kohn et al. would not be able to

perform. Therefore, the claims 30-32, 46, and 62 are considered obvious over Kohn et al.

Conclusion

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12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/ Ph.D.

Primary Examiner, Art Unit 1647